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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,545	11/12/1999	KENJI SHIBATA	2139.15	6874

5514 7590 02/24/2004

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EXAMINER

GUPTA, ANISH

ART UNIT PAPER NUMBER

1654

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,545

Applicant(s)

SHIBATA ET AL.

Examiner

Anish Gupta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 4-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. The amendment filed, 12-2-03, has been entered. Claim 1, 15, and 16 were amended and claim 17 was added. Claims 1-17 are pending in the application.

Election/Restriction

2. Applicant's election of the species of Compound 23, SEQ ID NO. 31 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

A search was conducted for the elected species of SEQ ID. NO. 31 and then extended to SEQ. 5 in the previous office action. In light of the amendment, the sequence search was again extended to SEQ ID NO. 1-4, 6-7, 16-30 and 32. No prior art was found on the elected species and, in accordance with the MPEP, the search of the Markush - type claim was be extended. Prior art was found that anticipates or renders obvious the Markush - type claim. The Markush - type claim is rejected and claims to the non - elected species held withdrawn from further consideration. Thus, claims 4-14 are withdrawn from consideration as corresponding to a non-elected species.

3. All rejection made in the previous office action are hereby withdrawn and new grounds of rejections follow below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As currently amended, the claims require the presence of R1 and R2. Thus, the cyclization occurs through side chains rather than the N- and C- terminus of the peptide. However, claims 15 and 16 both claim SEQ ID. No. 5 which cyclizes through the N- and C- terminus Leu residues. This sequence does not have a R1 variable or R2 variable. Further, in Seq ID. 21, the cyclization occurs through the N terminus Leu and side chain of the Lysine in the 1st position. The bond formed in the cyclization is a CO-NH₂, thus using the carboxy group of the Leu and the NH₂ of the lysine side chain. This sequence does not have present any group conforming to the R2 residue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohta et al.

The claims are drawn to a peptide corresponding to formula (I) which are cyclized and have at least 7 amino acids.

The reference teaches the peptide Cys-(Lys)₅-Cys wherein the Cysteine forms a di-sulfide bond (see col. 3, 4, seq. Id. 13). The peptide disclosed anticipates the claimed invention when X1 is

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allowed to be cysteine, X8-X12 are all lysine and X13 is cysteine. Note that since the cyclization occurs through the Cysteine side chain (di-sulfide linkage), the N-terminus H would be R1 and the C-terminus OH would be R2 of the peptide. Further, given the use of the X variables, q would be greater than p and thereby meeting the limitation of claim 3. The length of the amino acid sequence is 7, thereby meeting the limitation of claim 1. Although the reference does not teach the DNA-binding activity or P53 protein-dependent transcription activity, such a limitation is an intended use limitation. An intended use limitation and intended use or field of use for the invention generally will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra*.

6. Claims 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Hardy et al.

The claims are drawn to a peptides corresponding to formula (I) which are cyclized and have at least 7 amino acids.

The reference discloses the sequence CGGGGGC (see abstract and corresponding structure). This reference reads on the claims when R1 and R2 form a di-sulfide bridge, X1 is cys, X2-X6 is gly, and X7 is cys. Although the reference does not teach the DNA-binding activity or P53 protein-dependent transcription activity, such a limitation is an intended use limitation. An intended use limitation and intended use or field of use for the invention generally will not limit the scope of a

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claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra*.


7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta
Patent Examiner


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600